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REMARKS

This is responsive to the Office Action mailed on April 27, 2006. In the Office Action, claims 1-3, 5-20, 31 and 32 were rejected. The Application currently includes claims 1-3, 5-20, 31 and 32. Reconsideration of the claims is requested.

The Office Action rejected independent claim 1 as being anticipated under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,263,680 (Reul Patent). The Office Action alleges that the Reul Patent discloses a medical device (prosthetic heart valve at col. 6, line 29) that comprises a composite (valve member 1, col. 5, line 41) having an inorganic substrate (metal substrate 12, col. 5, ll. 45-47) and a polymer applied on all of the substrate surfaces (blood-compatible synthetic material 14, col. 5, ll. 41-44). The Office Action alleges that the polymer forms a structure shaped differently from the structure of the substrate and provides a form of the device (FIG. 3, hinge flap is formed in one piece with the valve member) and consists of the same blood-compatible synthetic material with which the valve member is coated, integrally cast in the course of the coating process (col. 4, ll. 39-45). The Office Action alleges that the valve ring is coated with the same blood-compatible synthetic material as the valve member at col. 4, ll. 47-49.

Applicant respectfully disagrees that independent claim 1 is anticipated by the Reul Patent. An element of independent claim 1 includes covering an inorganic substrate with a polymer applied on all of the substrate surfaces where the polymer forms a structure that is shaped differently from the structure of the substrate, the polymer providing the form of the device.

Contrary to the allegations contained in the Office Action, the Reul Patent does not disclose the application of a polymer on all substrate surfaces where the polymer forms a structure shaped differently from the structure of the substrate. Referring to col. 4, ll. 23-25, the Reul Patent discloses using a dipping process to coat the polymer onto the inorganic substrate.

A dipping process would place a layer having a substantially uniform thickness onto the inorganic substrate that conforms to the general shape of the substrate. A polymer coating of a

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substantially uniform thickness does not provide a structure that is shaped differently from the structure of the substrate as claimed. Rather, the polymer coating disclosed in the Reul Patent conforms to the shape of the substrate.

Therefore, the Reul Patent does not disclose a medical device where the polymer coated on the substrate forms a structure shaped differently from the structure of the substrate. As such, the Reul Patent does not anticipate independent claim 1. Reconsideration and allowance of independent claim 1 are respectfully requested.

The Office Action rejected independent claim 10 under 35 U.S.C. § 102(b) as being anticipated by the Reul Patent. The Office Action alleges that the Reul Patent discloses a medical device which is a prosthetic heart valve (col. 6, line 29,) which comprises a composite component having an inorganic substrate (metal substrate 12, col. 5, ll. 45-49) and a polymer member covering the substrate (blood-compatible synthetic material 14, col. 5, ll. 41-44) where the composite component can be bent through a cross-section of the composite component (thin valve member including metal substrate can be bent, 0.3 to 0.4 mm, col. 3, ll. 40-45) and wherein the polymer member contacts bodily fluid and separates the bodily fluid from the substrate (blood-compatible synthetic material, col. 4, ll. 40-45). The Office Action alleges that the composite component is flexible by virtue of its thickness (less than 0.3-0.4 mm, col. 3, ll. 40-42) in its composition (thin metal substrate, col. 5, ll. 45-46) and coating of blood-compatible synthetic material (col. 5, ll. 41-44,) which is flexible, flap made from the same (col. 6, ll. 44-46, col. 4, ll. 39-45).

Applicant respectfully disagrees that independent claim 10 is anticipated by the Reul Patent. An element of independent claim 10 includes a flexible composite component comprising an inorganic substrate and polymer member covering the substrate wherein the flexible composite component can be bent through a cross-section of the flexible component composite.

There is no disclosure that the Reul Patent discloses a heart valve member that can be bent through a cross-section. The Office Action alleges that because the valve member has a thickness of 0.3-0.4 mm, it must inherently flex. However, there is no disclosure that the heart valve member would flex. Further, a valve member that flexes would make the valve member

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less responsive in its opening and closing function which is in direct contrast to the advantages stated of the valve member as stated in the Reul Patent.

This has the advantage that, compared to traditional valves, very short opening and closing times can be achieved, since the moment of inertia of the thin dish is very small in comparison with spherical or disc valves. This fact guarantees that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber and thus resembles a natural valve more closely than any other existing artificial heart valve. Col. 3, ll. 42-58.

A reduction in weight of the valve member to decrease the moment of inertia does not lead to the conclusion that the valve member flexes. If the valve member flexed, some of the energy created by the pressure gradient would have to be directed into forcing the valve member to flex, thereby decreasing the responsiveness of the valve to the pressure gradient. The decreased responsiveness is due to it being a two-step process: first flexing the valve member and then moving the valve member about a pivot. This is contrary to the responsiveness teachings of the Reul Patent. As such, there is no teaching in the Reul Patent that the valve member for an artificial heart valve flexes.

For the foregoing reasons, the Reul Patent does not disclose a flexible composite component of a medical device that can be bent through a cross-section of the flexible component. Therefore, the Reul Patent does not anticipate independent claim 10. Reconsideration and allowance of independent claim 10 are respectfully requested.

The Office Action also rejected claims 2, 3, 8, 9, 11, and 16-19 as being anticipated by the Reul Patent. The Office Action also rejected claims 5-7, 12-14, and 31-32 as being obvious over the Reul Patent in view of the Peitsch Patent. The office Action also rejected claim 15 as being obvious over the Reul Patent in view of the Lenkei Patent. The Office action also rejected claim 20 as being obvious over the Reul Patent in view of Sumitomo Electric Co. Abstract. While Applicants do not acquiesce to any of the claim rejections, the rejections are moot in light of the fact that independent claims 1 and 10 are in allowable form. Since independent claims 1 and 10 are in allowable form, it follows that dependent claims 2, 3, 5-9, 11-20, and 31 and 32 are

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in allowable form. Reconsideration and allowance of claims 2, 3, 5-9, 11-20, and 31 and 32 are respectfully requested.

In view of the reasons provided above, it is believed that the pending claims are in condition for allowance. Applicant respectfully requests favorable consideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Hallie A. Finucane at 612-334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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